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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,942	06/02/2000	Daniel Flammang	39558/DBP/E43	6577

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VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP  
P.O. BOX 34385  
WASHINGTON, DC 20043-9998

EXAMINER
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OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/586,942

Applicant(s)

FLAMMANG, DANIEL

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 21.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Withdrawal of Finality***

1. The Examiner called the Applicant's agent, Ms Voorhees, seeking to place the appealed application in better condition for allowance by addressing two 35 U.S.C. 112 issues.

Ms. Voorhees and Examiner Oropeza were unable to come to an agreement on amendments to claim 20, hence the finality of the last office action is withdrawn. With this paper, a non-final office action issued to address the 35 U.S.C. 112 issues of record.

### ***Claim Rejections - 35 USC § 112***

2. Claims 14-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

Claim 20 is indefinite because the Examiner is unclear whether the subcombination of the electrode arrangement or the combination of the electrode arrangement and the electrical pulse-discharging device is claimed. Clarification is needed.

In claim 23, "the ring electrodes" lack antecedent basis.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102/ 35 USC § 103***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 14 and 19-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McGee et al. (US 5855592) in view of Ljungstrom (EP 0 601 328 A 1).

As to claim 20, Mc Gee et al. disclose a multi-site cardiac defibrillation system comprising an electrode arrangement (10) having a lead (12) with an undivided proximal end (14), a distal end (16) and an electrode support assembly (20) with spline elements (22) (branches) (col. 5 @ 66 – col. 6 @ 10). In the figure 6 embodiment, an electrical pulse-discharging device (58) is connected to one or more arrays of electrodes (70), each array having a splitter (72) and branches (67) with a central core structure made of memory wire (a memory member structure). Eight electrodes (67) are disposed on each branch (col. 14 @ 29-61). The number of branches can be eight or fewer, read to be two branches (col. 6 @ 32-36). The characteristic of “unambiguously associated” electrodes is accepted to be electrodes from different lead branches grouped to stimulate a defined area. If the plurality of electrodes is read as two electrodes, each branch has a single electrode, hence creating a single region where the two electrodes are unambiguously associated (col. 3 @ 13-20; col. 4 @ 13-19). If the plurality of electrodes is read as to be an even number of electrodes, each branch has an equal number of electrodes and the electrodes on the first and second branches create a pair of unambiguously associated electrodes, hence creating bands/ regions of stimulated myocardium (col. 7 @ 60-64; col. 8 @ 15-21; col. 9 @ 60-65). Note that the concept of contacting the “lateral and septal” regions amounts to an intended use limitation of which McGee is inherently capable of performing.

As to claim 14, the slidable sheath (44) (sliding sleeve) is deployed by adjusting the sheath using a rearward movement (arrow 43) (figures 3 and 4; col. 6 @ 37-63).

As to claim 18, the memory member structure contains titanium (col. 6 @ 8-10).

As to claim 19, the electrode arrangement has three different branches (figure 6).

As to claim 21, the branches each contain eight electrodes (about seven electrically conductive surface portions) (figure 6).

As to claims 22 and 23, the conductive surface portions are ring electrodes, one ring electrode located at the distal end of each branch (col. 14 @ 45-48).

As to claim 24, the electrodes are spaced one centimeter apart (col. 9 @ 53-55).

As noted above, the number of branches can be eight or fewer, read to be two branches, the lateral and septal branches (col. 6 @ 32-36).

In the alternative, given that McGee et al. do not explicitly call for lateral and septal branches, Ljungstrom teaches electrode arrangements using a two limb-shaped structure to uniformly distribute the conductors over the electrode head for the purpose of providing a comparatively large defibrillation area. Based on the location of the limbs/ branches in figure 4, the two branches are named the septal branch (19) and the lateral branch (18). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the McGee branches in the septal and lateral areas of the heart in order to uniformly distribute the electrodes over the atrium providing optimal atrial tissue stimulation (figure 4; page 3 @ 5-11).

***Claim Rejections - 35 USC § 103***

5. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGee et al. (US 5855592) in view of Cookston et al. (US 5834031), or in the alternative, under 35 U.S.C.

103(a) as obvious over McGee et al. (US 5855592) in view of Ljungstrom (EP 0 601 328 A 1) and further in view of Cookston et al. (US 5834031). As discussed in paragraph 4 of this action, McGee et al./modified McGee et al. disclose the claimed invention except for a means for heating the memory member structure.

Cookstone et al. teach lead placement using ohmic heating for the purpose of deflecting the memory member in the lead to enhance electrode contact with a desired heart region. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used ohmic heating in the McGee et al./ modified McGee et al. system in order to effect proper lead contact and to avoid excessive lead implantation cost associate with lead damage and increased operating time (figures 4-6: col. 1 @ 7-20 and 28-31; col. 2 @ 11-39; col. 3 @ 31-45; col. 7 @ 3-65).

6. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGee et al. (US 5855592) in view of Hess (US 4664120), or in the alternative, under 35 U.S.C. 103(a) as obvious over McGee et al. (US 5855592) in view of Ljungstrom (EP 0 601 328 A 1) and further in view of Hess (US 4664120). As discussed in paragraph 4 of this action, McGee et al./modified McGee et al. disclose the claimed invention except for the lead configuration including two branches and a ventricular branch with at least one ventricular electrode.

Hess teaches multifunctional lead design using a configuration including two branches and a ventricular branch with at least one ventricular electrode for the purpose of establishing and maintaining reliable contact with portions of the heart undergoing testing and/ or treatment. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a lead configuration including two branches and a ventricular branch with at least one

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ventricular electrode in the McGee et al./ modified McGee et al. system in order to effectively and efficiently perform multiple functions, such as mapping or pacing, in connection the diagnosing or treatment of cardiac conditions (col. 1 @ 7-13; col. 2 @ 21-31; figures 4 and 5).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

*FPO*  
*3/10/03*

*[Signature]*  
JEFFREY R. JASTRZAB  
PRIMARY EXAMINER

*3/10/03*